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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|----------------------|----------------------|---------------------------|------------------|
| 10/535,624 | 10/25/2005 | In-Hee Lee | 2393.0010000/JUK/SMW | 1731 |
| 26111 STERNE KES | 7590 10/16/200° | EXAMINER | | |
| STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. | | | GUDIBANDE, SATYANARAYAN R | |
| WASHINGTO | WASHINGTON, DC 20005 | | ART UNIT | PAPER NUMBER |
| | | | 1654 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 10/16/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|--|---|----------------------|----------|--|--|--|
| Office Action Commence | 10/535,624 | LEE ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Satyanarayana R. Gudibande | 1654 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | | | • | | | |
| · · · · · · · · · · · · · · · · · · · | action is non-final. | | | | | |
| 3) Since this application is in condition for allowar | | secution as to the m | erits is | | | |
| closed in accordance with the practice under E | x parte Quayle, 1935 C.D. 11, 45 | 3 O.G. 213. | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1-11 is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdraw | vn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | • | | | |
| 6) Claim(s) is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | • | | | | | |
| 8) \boxtimes Claim(s) <u>1-11</u> are subject to restriction and/or \in | election requirement. | | | | | |
| Application Papers | | | | | | |
| 9) ☐ The specification is objected to by the Examine | r. | | | | | |
| 10) The drawing(s) filed on is/are: a) acce | epted or b) objected to by the E | Examiner. | | | | |
| Applicant may not request that any objection to the | drawing(s) be held in abeyance. See | e 37 CFR 1.85(a) | • | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | |
| Certified copies of the priority documents | s have been received. | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | |
| | 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | , | | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) Linterview Summary Paper No(s)/Mail Da | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 5) Notice of Informal P 6) Other: | | | | | |

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, drawn to a peptide separated from tunicate comprising amino acid sequence represented by chemical formula 1.

Group II, claim(s) 5-7, drawn to a chemical formula 2.

Group III, claim(s) 8, drawn to a peptide represented by chemical formula 3.

Group IV, claim(s) 9, drawn to a peptide represented by chemical formula 4.

Group V, claim(s) 10 drawn to a peptide represented by chemical formula 5.

Claim 11 link(s) inventions I-V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 11. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory

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double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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According to PCT Rule 13.2, unity of invention exists only when the shared or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-V do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Group I is a peptide comprising amino acid sequence represented by the chemical formula 1, which is shown by Jang, et al., 2002, FEBS Letters, 521, 81-86 that discloses the peptide WLNALLHHGLNCAKGVLA that corresponds to SEQ ID NO:1 of the instant invention (claim 4 of the instant invention) and hence the special technical feature of invention of group I does not make a contribution over the prior art. Therefore, the inventions groups I-V lacks unity of invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species

This application contains claims directed to the following patentably distinct species of peptides represented by formulae 1-5. The species are independent or distinct because claims to the different

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species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of peptide with a SEQ ID NO., associated with the elected species or applicants are required to clearly specify all the variables in the formula so that the elected species represents a single peptide with a defined structure for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3 and 5-10 are generic.

Claim 11 is generic to the following disclosed patentably distinct species: an antimicrobial agent. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of antimicrobial agent with a SEQ ID NO., or structure with all the variables clearly identified to represent a single species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

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Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above <u>and</u> there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Satyanarayana R. Gudibande, Ph.D.

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